

## **RESPONSE**

### **REMARKS**

#### **Election Requirement Withdrawn**

The OA under reference mailed 06/07/2007 states that the previous election requirement has been withdrawn and that claims 53-63 and 66-100 are in the prosecution case, and these claims have been examined.

#### **Rejection under 35 USC § 112, second paragraph**

The OA rejects claims 56-61 and 66-100 under the second paragraph of 35 USC § 112 as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as his invention. In particular, the use of the phrase 'prehydrated amphiphilic molecules' in claim 56 is alleged to be unclear, the phrase 'said selected agent' in claims 57, 61, 63-76 and 97 is alleged to lack an antecedent basis, the terminology 'proving [providing] a liposome, lipid complex or biological cell' is alleged to be confusing, and claims 75 and 78-79 are deemed to be indefinite because these claims refer to Table numbers in the specification without a specific reason. These rejections are successfully overcome in the succeeding paragraphs.

#### ***Prehydrated amphiphilic molecules***

The OA alleges that the phrase 'prehydrated amphiphilic molecules' in claim 56 which is dependent on claim 57 is unclear because according to claim 57, the amphiphilic molecules are already in an aqueous solution, which means they are hydrated. The Applicant traverses and respectfully submits that the method of claim 57 does not recite amphiphilic molecules in aqueous solution; rather, the method of claim 57 recited in lines 1-3 comprises admixing (i) an aqueous solution or phase, and (ii) a population of lipid components with a population of amphiphilic molecules. The term 'prehydrated' is clearly understood in the art, and has been used herein in the claims and in the specification at least on page 21, line 3-7 in its common usage meaning. However, in order to progress the present application to allowance in a timely and cost-effective

manner, Applicant has amended claims 56, 57 and 97 as follows essentially by adapting the Examiner's suggestions:

**Claim 56:** The phrase 'prehydrated amphiphilic molecules' has been deleted and the phrase 'in a prehydrated state' substituted therefor.

**Claim 57:** The phrase ', the said amphiphilic molecules being taken as such or in a prehydrated state' has been added in claim 57, line 3; in addition, in line 6, the phrase 'a selected chemical or biological agent or cell' has been deleted and the phrase 'a selected agent comprising a chemical agent or a biological agent or a biological cell' has been substituted therefor.

**Claim 97:** In Claim 97 part (b) line 1, the phrase 'said selected agent' has been deleted and the phrase 'a selected agent comprising a chemical agent or a biological agent or a biological cell' substituted therefor.

Explicit support for the original terminology 'prehydrated amphiphilic molecules' is found in the specification at least on page 21, lines 3-7. The phrase 'amphiphilic molecules are in a prehydrated state' will be seen as a permissible functional equivalent of the original 'prehydrated amphiphilic molecules.'

***Lack of antecedent basis***

The OA alleges that the phrase 'said selected agent,' on the last line of claim 57 and in claims 61, 63-67 and 97, lacks an antecedent basis. The Applicant traverses and respectfully submits that the scope of the subject claims as presented already can be determined by one having ordinary skill in the art and thus the rejection using this form paragraph is not appropriate. Specifically, the phrase 'a selected chemical or biological agent or cell' in line 6 of claim 57 as examined, will be seen as the required and sufficient antecedent in the independent claim 57 and claims 61, 63-67 and 97 which are directly or indirectly dependent on claim 57. However, in the interest of taking this application to

allowance without additional delay, the applicant has amended claims as above essentially according to the Examiner's suggestions.

***Terminology is confusing***

The OA alleges that Claim 58 recites 'proving [providing] a liposome, lipid complex or biological cell. This terminology is confusing.' The Examiner suggests restructuring presumably to the original independent claim format. The examined claim explicitly and unambiguously recites the claimed invention as the method comprising 'contacting a liposome or lipid complex or biological cell with an amphiphilic material (of the present invention)' whereby the said a liposome or lipid complex or biological cell becomes coated with the amphiphilic material (of the present invention). Moreover, prehydrated amphiphilic molecules can be in other distinct state, e.g., a hydrated crystal. The Applicant has adapted Examiner's suggestion as follows: In claim 58, the text '(a) providing a liposome, lipid complex or biological cell; and (b) contacting said liposome, lipid complex or biological cell with an amphiphilic material that comprises' has been deleted, and the text 'contacting or admixing, in an excess of an aqueous solution or phase, a liposome or lipid complex or biological cell, with an amphiphilic material comprising a population of amphiphilic molecules, preferably prehydrated amphiphilic molecules,' has been substituted therefor; in addition, the first occurrence (line 5) of "wherein" has been deleted and "whereupon" substituted therefor, the second occurrence (line 7) of 'wherein' has been deleted, and the two occurrences of the word 'cell' (lines 7 and 9) have been deleted and the phrase 'biological cell' has been substituted therefor. Thus dependent claim 58 has been restructured and further amended to conform to the currently amended parent claim 57; it could be converted into an independent form by deleting in line 1, the phrase 'of claim 57 further'.

**Claims should not refer to Tables in the Specification**

The Action rejects claims 75 and 78-79, alleging that references to tables are improper without a specific reason. Applicant respectfully submits that in the present case, it is more concise to incorporate by reference than duplicating 3 tables into the claim. This is sufficient specific reason as the Board Pat. App. & Inter has stated that

incorporation by reference is permitted "where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter., 1993). Although the Board in *Ex parte Fressola* upheld the rejection of the only appealed claim (claim 42), this claim was an "omnibus" or "formal" claim, which attempted to define the invention entirely by reference to specification and drawings. Current claims 75 and 78-79 are not omnibus or formal claims, but particularly point out and distinctly claim the invention by acceptable and concise reference to Tables in the specification. Moreover, the Examiner previously has accepted, albeit after the Applicant proffered the foregoing rationale, reference to the same Tables in claims allowed in the grand parent application Ser. No.08/912,978 now US6,284,267, as well as the parent Ser. No. 08/912,978 now US6,699,499.

**Claims 75 and 78-79:** Original claims 75 and 78-79 thus already are presented in clear and acceptable form, the rejection is overcome.

#### **Rejection of Claims for Obviousness-Type Double Patenting - Terminal Disclaimer**

The OA rejects claims 53-55, 62 and 98-100 on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-57 of US Patent No. 6,284,267 and claims 1-45 of US 6,699,499, even though the present claims are considered (by the OA) not identical with the claims in the Applicant's prior US patents.

The OA alleges that the pending claims and the claims in the '267 patent are not patentably distinct from each other because the '267 claims "recite the same amphiphilic material and formulations which are liposomes or aggregates or other forms and instant claims 53-55 and 98-99 which recite liquid-crystalline multimolecular aggregates or liposomes are obvious variants. To prepare the composition in the kit form would have been obvious to one of ordinary skill in the art since the medical arts compositions are often used in a kit form" (Action at Item 4, page 3-4). The OA analogously argues that claims 53-55, 62 and 98-100 as being unpatentable over claims 1-45 of US 6,699,499.

The present application was filed as a proper divisional application based on claims which were not entered, neither in the grand parent application Ser. No.08/912,978 now US6,284,267, and nor subsequently in the parent Ser. No.

08/912,978 now US6,699,499, because during prosecution these un-entered claims were considered by the PTO to be drawn to a distinct invention and subject of imposed restriction and election requirements. Further, it is matter of record that after a prolonged history of multiple office actions each seeking to impose distinctly different restriction requirements, all restriction requirements seeking to split pending claims in the present application into multiple inventions have been withdrawn. The present obviousness-type double patenting rejections are therefore improper and overcome, and should be withdrawn.

Nonetheless, without acquiescing with the present rejection in any way, and solely to progress the present application to allowance as quickly as possible, Applicant elects to provide a Terminal Disclaimer, and respectfully requests the Examiner to enter the enclosed Terminal Disclaimer, Fee and Statement under 37 CFR 3.73(b), as timely filed. The Applicant notes the case law is clear that the filing of a Terminal Disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. vs. Union Sanitary District*, 20 USPQ2d 1392 (Fed. Cir. 1991).

### **Conclusion**

The present document and enclosures constitute a complete response to the OA under reference mailed 06/07/2007. In light of the remarks herein, the present application is in condition for allowance and such action is respectfully requested. Should Examiner Kishore have any questions or comments, a telephone call to the undersigned Applicant acting *pro se* is earnestly solicited.

Respectfully submitted,



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